EXHIBIT A

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In Re: Valsartan Products Liability Litigation **MDL No: 2875**

PLAINTIFFS' MOTION TO EXPAND THE SCOPE OF MDL NO. 2875 TO INCLUDE CASES INVOLVING OTHER CONTAMINATED ANGIOTENSION II RECEPTOR BLOCKERS ("ARBS")

Oral Argument Requested

COME NOW, Plaintiffs represented by Co-Lead Counsel appointed by the District Court to which this MDL is assigned (*see* Ex. B to the accompanying memorandum), and respectfully move the Panel for an Order: (1) expanding the scope of this MDL No. 2875, *In re Valsartan Products Liability Litigation* to include all federal cases concerning Angiotensin Receptor Blockers ("ARB's") contaminated with carcinogenic contaminants, and (2) renaming this MDL as *In re ARB Contamination Products Liability Litigation*. The reasons supporting this motion are set forth in the accompanying memorandum of law.

Respectfully submitted, this 21st day of August 2019,

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In Re: Valsartan Products Liability Litigation **MDL No: 2875**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO EXPAND THE SCOPE OF MDL NO. 2875 TO INCLUDE CASES INVOLVING OTHER CONTAMINATED ANGIOTENSION II RECEPTOR BLOCKERS ("ARBS")

I. INTRODUCTION

This MDL, No. 2875, pending before the Honorable Robert B. Kugler in the District of New Jersey, currently involves contaminated generic drug products containing valsartan, a medication indicated for the treatment of high pressure and other conditions. Valsartan is one of multiple drugs in the class known as angiotension II receptor blockers ("ARBs").

Investigation by the U.S. Food and Drug Administration ("FDA") discovered that the production processes at certain overseas manufacturing facilities resulted in valsartan-containing drugs being contaminated with a known carcinogen (described more below) known as N-Nitrodimethylamine (NDMA). As a result, the FDA announced a recall of certain valsartan-containing drugs on July 13, 2018. The agency subsequently expanded its investigation into the entire ARB drug class, and recalled valsartan drugs containing N-Nitrosodiethylamine (NDEA).

The FDA's investigation into other ARBs was still in its infancy when this Panel created MDL No. 2875 in early February 2019. But now, at least 529 lots of two other ARBs – losartan and irbesartan – have been recalled due to the same type of contamination as that with valsartan.[1] The upward trend of ARB recalls shows no signs of abating – as of June 18, 2019, there were 496 recalled lots of losartan and irbesartan alone; less than two months later, that number is now up to 529. In some instances, the exact same companies manufacture or sell multiple contaminated

[1] FDA SEARCH LIST OF RECALLED ANGIOTENSION II RECEPTOR BLOCKERS (ARBS) INCLUDING VALSARTAN, LOSARTAN, AND IRBESARTAN, *at* https://www.fda.gov/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and (last accessed August 6, 2019).

ARBs (e.g., losartan, irbesartan, and valsartan). Notably, the FDA has found ARB drugs to be contaminated with multiple different carcinogens, not just NDMA and NDEA, and it is the current understanding that this contamination has been occurring during the manufacturing process of the various API's. This is described in more detail below.

When the Panel created MDL No. 2475, it expressly reserved judgment on whether this MDL would grow to include actions involving other ARBs and/or other contaminants besides NDMA and NDEA, because at that time merely a couple of "irbesartan and losartan actions [had been] filed only in recent days." *See* ECF 229 at 3. Thus "[t]he record on the factual issues involved in those actions [was] not sufficient for the Panel to make such a determination." *Id.*

The record is now further developed. The FDA's ongoing investigation has confirmed that the same manufacturing issues that resulted in valsartan being contaminated with a carcinogen have also resulted in losartan and irbesartan being contaminated with the same or similar carcinogens.[2] Actions for economic loss and personal injury arising from the marketing of contaminated losartan and irbesartan, based on the same fact patterns and theories as those in this MDL, have been and will continue to be filed.

All of the ARB cases involve common questions of fact and law. Given this, the most fair, convenient, and efficient path is to expand this MDL to include all ARB actions involving any carcinogenic contaminant (not just NDMA). Accordingly, Movants respectfully ask that this MDL be expanded to include all ARBs and re-styled "*In re ARB Contamination Products Liability Litigation*."

[2] FDA STATEMENT ON THE AGENCY'S LIST OF KNOWN NITROSAMINE-FREE VALSARTAN AND ARB CLASS MEDICINES, AS PART OF AGENCY'S ONGOING EFFORTS TO RESOLVE ONGOING SAFETY ISSUE, *at* https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys (last accessed August 6, 2019) (noting the agency is in communication with manufacturers of all ARB medicines about how manufacturing processes could lead to the creation of unwanted impurities).

II. PERTINENT FACTS AND BACKGROUND

Valsartan is a generic version of the brand-name drug Diovan®, an angiotensin receptor blocker (ARB), used to treat high blood pressure and heart failure.

N-Nitrodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), and Nitroso-N-methyl-4-aminobutyric acid (NMBA) are odorless liquids that can be unintentionally produced through chemical reactions during manufacturing processes. NDMA, NDEA, and NMBA are known carcinogens. The pharmaceutical industry has been aware of the potential formation of NDMA, NDEA, or NMBA during manufacturing processes since at least 2005.

On July 13, 2018, the FDA announced a recall of certain valsartan-containing products due to their being contaminated with NDMA. The FDA's investigation rapidly expanded to include valsartan manufactured, distributed, or sold by multiple companies.

The scope and seriousness of the initial recall led the FDA to investigate all drugs in the ARB class.[3] As a result of this investigation, recalls involving other drugs in the ARB class have followed one after the other. Since the initial recall, the FDA has determined that the manufacturing issues leading to contamination of valsartan-containing drugs has also affected other ARBs, principally losartan and irbesartan, at this time. As of August 6, 2019, the FDA's official list of recalled ARB products concerning this contamination identifies 625 recalled lots of valsartan, 484 lots of recalled losartan, and 45 lots of recalled irbesartan.[4] These numbers, of course, only relate to ARB lots *currently* available on the market. They do not include lots sold in prior years.

To date, the FDA has found elevated levels not just of NDMA and NDEA, but also NMBA in valsartan and other ARB drugs.[5] For instance, in connection with its ongoing investigation and

[3] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[4] *See supra* n.1.
[5] *See, e.g.*, FDA UPDATES TABLE OF INTERIM LIMITS FOR NITROSAMINE IMPURITIES IN ARBS, *at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-

the related recalls – and after the Panel created this MDL – the FDA announced "Interim Limits for NDMA, NDEA, and NMBA in Angiotension II Receptor Blockers (ARBs)."[6] Recently, an independent firm's testing identified the presence of a fourth carcinogen, dimethylformamaide (DMF), in multiple companies' valsartan-containing drugs.[7]

On February 14, 2019, the Panel established *In re Valsartan Products Liability Litigation*, MDL No. 2875, and assigned this MDL to the Honorable Robert B. Kugler in the District of New Jersey, to encompass all industry-wide issues concerning the production of contaminated valsartan-containing drugs. *See* ECF 229 at 2. The Panel reserved judgment at that time as to whether other ARBs should be included as well given that only a couple of cases had been filed shortly before the Panel's January 31, 2019 hearing. *See* ECF 229 at 3.

Judge Kugler and Magistrate Judge Schneider have efficiently established control over this MDL. In the short time since its establishment, Judge Kugler and Magistrate Judge Schneider have held 9 case management conferences, entered 13 case management orders, entered an ESI Protocol, entered a discovery confidentiality order, entered an Order providing for the use of a short form complaint, ordered the production of preliminary "core discovery," resolved service of process issues, permitted the filing of three separate Master Complaints (all of which were filed in June), established a timeline for other initial discovery, and are actively overseeing the parties' preparation of, among other things, plaintiff and defendant fact sheets, and early dismissal applications for so-called "peripheral" defendants. The format and procedure used for each of these litigation wide pleadings and issues can be readily utilized for and applied to the losartan, irbesartan, and other ARB cases.

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receptor-blocker-arb-recalls-valsartan-losartan (identifying "Interim Limits for NDMA (last accessed Aug. 19, 2019).

[6] *Id.*

[7] *See, e.g.*, FOURTH CARCINOGEN DISCOVERED IN HEART PILLS USED BY MILLIONS, *at* https://www.bloomberg.com/news/articles/2019-06-18/fourth-carcinogen-discovered-in-heart-pills-used-by-millions (last accessed Aug. 19, 2019).

At present, at least 15 class actions and personal injury cases have been filed involving losartan or irbesartan around the country. *See* Ex. A (schedule of actions involving losartan or irbesartan). Two of these actions are already pending before Judge Kugler, but are not part of this MDL. Plaintiffs' counsel in this MDL have represented to Judge Kugler that they are actively vetting and intend to file many more losartan and irbesartan cases.

III. ARGUMENT

For the convenience of the parties and witnesses and to promote the just and efficient conduct of cases, the Panel is requested to expand the scope of MDL No. 2875 to include cases concerning other contaminated ARB's in addition to valsartan. The Panel is empowered to expand the scope of an existing MDL where the cases proposed to be consolidated involve common questions of fact with the actions in the existing MDL. *See, e.g., In re Generic Digoxin & Doxycycline Antitrust Litig.*, 222 F. Supp. 3d 1341, 1343-44 (J.P.M.L. 2017) (expanding scope of MDL No. 2724 beyond generic digoxin and doxycycline to include additional generic drugs that shared common questions of fact with the actions in MDL No. 2724); *In re Viagra (Sildenafil Citrate) Prod. Liab. Litig.*, 224 F. Supp. 3d 1330, 1332 (J.P.M.L. 2016) (expanding scope of MDL No. 2691 from cases involving only Viagra to include Cialis cases where both types of cases involved common questions of fact).

MDL No. 2875 already involves all actions alleging economic or personal injury arising out of contaminated valsartan-containing products. The Panel found that all valsartan actions share many common questions of fact, including

> (1) whether the generic valsartan sold by defendants contained NDMA or NDEA;
> (2) the cause of the alleged impurities, including alleged defects in the manufacturing and sampling process;
> (3) when defendants knew or should have known of the impurities;
> (4) how long the NDMA- and NDEA- containing valsartan medications were in circulation; and
> (5) whether the amounts of NDMA and NDEA in the medications presented a risk of cancer or other injuries.

Id. at 3. The Panel found that "[a]ll of the valsartan actions will raise these issues, regardless of" who the specific manufacturer or supplier was. *Id.* Additionally, the Panel found that "[c]entralization will eliminate duplicative discovery, prevent inconsistent pretrial rulings, including with respect to class certification and Daubert motions, and conserve the resources of the parties, their counsel, and the judiciary." *Id.*

Existing and to-be-filed actions involving other contaminated (or potentially contaminated) ARB's present the same common issues and will benefit from the same efficiencies now in place in the existing MDL. In fact, cases have been or will be filed involving individuals' use of multiple contaminated ARB's, thus consolidation of all ARB contamination cases is the most logical means to assure efficiency and coordination. All of the common questions and efficiencies identified above by the Panel with respect to centralization of the valsartan actions apply equally to other ARB actions. For example, the valsartan, losartan, and irbesartan actions also involve overlapping parties (e.g., some of the same defendants), and some of the same counsel for the parties on both sides. Centralization of all ARB cases involving contamination with any carcinogen (NDMA, NDEA, NMBA, DTF, etc.) is even more appropriate given that some losartan and irbesartan cases already are separately pending before Judge Kugler. Simply put, the key issue here – contamination of ARB drugs – is, in the FDA's words, a drug "class" wide issue.[8]

Current and future economic loss and personal injury actions involving allegedly contaminated ARBs, in addition to valsartan, will share many common questions of fact relating to the presence, reasons, and consequences of the contamination. The same fact discovery (e.g., production records, regulatory inspection reports, sales data, etc.) and expert discovery (e.g., manufacturing processes, general causation, etc.) will be sought or developed in each case.

[8] https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys/

Centralization will serve the convenience of the parties and witnesses, and will promote the just and efficient conduct of the litigation. *See, e.g.*, *In re AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379-80 (J.P.M.L. June 6, 2014) (centralizing actions against multiple manufacturers of competing testosterone-replacement therapy products); *In re: Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345 (J.P.M.L.2013) (centralizing actions against competing defendants which manufactured four similar diabetes drugs that allegedly caused pancreatic cancer); *See also In re Preempro Prods. Liab. Litig.*, MDL No. 1507 (originally centralized to include only Wyeth's hormone replacement therapy products but later expanded to include other Wyeth products and the drugs of other manufacturers).

The just and efficient resolution of all claims relating to the class-wide ARB contamination through a single centralized MDL proceeding will be maximized by the requested expansion of the existing MDL. The District of New Jersey, and Judge Kugler in particular, is the appropriate transferee forum for all ARB cases. Judge Kugler has already demonstrated his ability and willingness to actively manage this MDL, and will not need to re-invent the wheel were this MDL expanded to include all contaminated ARB's. *See, e.g.*, *In re Coloplast Corp. Pelvic Support Sys. Prods. Liab. Litig.*, 883 F. Supp. 2d 1348, 1349 (J.P.M.L. Aug. 6, 2012) (transferring new pelvic repair cases to existing MDL to avoid disruption of ongoing pretrial proceedings, where at least some defendants were already parties in the existing MDL). Further, in terms of convenience, many of the valsartan, losartan, and irbesartan defendants have their headquarters or substantial operations in New Jersey, including Hereto USA, Inc., Camber Pharmaceuticals, Inc., Torrent Pharma, Inc. and Teva Pharmaceuticals USA, Inc. *See, e.g.*, ECF 229 at 5 (identifying New Jersey operations of some of these same defendants in the valsartan actions).

IV. CONCLUSION

For the foregoing reasons, Movants respectfully request that the Panel expand the scope of MDL No. 2875, *In re Valsartan Products Liability Litigation* to include cases concerning all ARB drugs and carcinogenic contaminants, and that the MDL be renamed *In re ARB Contamination Products Liability Litigation*.

Respectfully submitted, this 21st day of August 2019,

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BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In Re: Valsartan Products Liability Litigation **MDL No.: 2875**

AMENDED SCHEDULE OF ACTIONS INVOLVING OTHER ARB DRUGS

Economic Loss Cases

Case Name	Civil Action Number & Court	Drug(s) Identified
Wineinger v. Solco Healthcare, et al.	No. 1:19-cv-01070 (D.N.J.)	Irbesartan
Patras v. Torrent Pharmaceuticals, Inc., et al.	No. 1:19-cv-11497 (D.N.J.)	Losartan
Sanders v. Torrent Pharma, Inc.	No. 1:19-cv-12745 (D.N.J.)	Losartan
Roddey v. Camber Pharmaceuticals, Inc.	No. 19-cv-12763 (D.N.J.)	Losartan

Personal Injury Cases

Case Name	Civil Action Number & Court	Drug(s) Identified
Noe v. Hetero Labs, Ltd., et al.	No. 4:19-cv-00054 (W.D. Ky.)	Losartan and Valsartan
Estate of Larry Brock v. Teva Pharmaceutical Industries Ltd., et al.	No. 4:19-cv-00538 (E.D. Ark.)	Losartan
Thomas v. Hetero Drugs, Ltd., et al.	No. 6:19-cv-01290 (N.D. Ala.)	Losartan
Bennett et al v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	No. 2:19-cv-02418 (W.D. Tenn.)	Irbesartan
Branham v. Hetero Drugs, Ltd., et al.	No. 3:19-cv-00265 (E.D. Tenn.)	Valsartan and Losartan

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: Valsartan Products Liability Litigation **MDL No: 2875**

AMENDED PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that a copy of the foregoing Motion to Expand the Scope of MDL No. 2875 to Include Cases Involving Other Contaminated Angiotension II Receptor Blockers ("ARBs"), Memorandum, and Exhibits in Support of the Motion were electronically served on registered users through CM/ECF system, or as otherwise indicated below, on August 27, 2019:

Brian Wineinger, et al. v. Solco Healthcare, et al. **U.S.D.C. for the District of New Jersey; Case No: 1:19-cv-01070**	
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Estate of Larry Brock v. Teva Pharmaceutical Industries Ltd., et al. **U.S.D.C. for the Eastern District of Arkansas; Case No: 4:19-cv-00538**	
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Stacey Thomas v. Hetero Drugs, Ltd., et al. **U.S.D.C. for the Northern District of Alabama; Case No. 6:19-cv-01290**	
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Myra Bennett, et al. v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al **U.S.D.C. for the Western District of Tennessee; Case No. 2:19-cv-02418**	
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Norma Branham v. Hetero Drugs, Ltd., et al. **U.S.D.C. for the Eastern District of Tennessee; Case No. 3-19-cv-00265**	
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Dated: August 27, 2019

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